NOV - 9 2000

8. 510 K summary
CBW micro handpiece and micro bur

K002693

Submission date : August 25 , 2000

Submitter :
CBS International BV
Grote Markt 3-5
1315 JA Almere
The Netherlands

Contact
Patricia Jansen
Tel : + 31 36 5302005
Fax : +31 36 5302004
e-mail : info@crownless-bridge-works.com

Device Name
Trade name : CBW micro handpiece , CBW micro burs
Common name :handpiece, dental burs
Classification name : handpiece, dental, gear driven (C.F.R. 872.4200) burs, dental (C.F.R. 872.3240)

Device Description and Comparison to Predicate Products
The CBW micro handpiece and micro burs are intended for use in a specific dental operatory : to prepare precise dental cavities .The handpiece and burs are similar in function, material and intended use to other dental handpieces and burs currently in U.S. commercial distribution. E.g. KaVo Handpieces marketed by KaVo America Corporation , 2401 West Hassel Road, Hoffman Estates, Illinois 60195 or Lynx Handpieces marketed by MTI Precision Products, 175 Oberlin North Avenue, Lakewood, New Jersey 08701.
The CBW micro handpiece has an E-Type coupling and is fully autoclavable (up to 135° C)
The CBW micro bur is made of steel nr. 1.4034, hardened 50-55 HRC

Performance testing
The CBW micro handpiece and micro burs, CE-Mark 0301, comply with ISO standard 7785-2 for dental handpieces Part 2 straight and geared angle handpieces, ISO standard 3964 for dental handpieces-coupling dimensions and ÖN EN 1639 for medical instruments . The manufacturer CBS International BV is ISO 9002 certified. The CBW micro handpiece and micro burs comply with harmonized standards according to the derective for medical devices 93/42/EEC, EN 46002, EN 1441 standards

7. 510 K summary
CBW anchors

Submission date : August 25 , 2000

Submitter :
CBS International BV
Grote Markt 3-5
1315 JA Almere
The Netherlands

Contact :
Patricia E. Jansen
Tel. +31 36 5302005
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e-mail : info@crownless-bridge-works.com

Device Name
Trade name : CBW anchors
Common name : pins or anchors
Classification name : we were unable to find such a device listed in the classification regulations

Description / intended use and comparison to predicate products : to increase mechanical retention of adhesive bridges by placing CBW anchors (pins) in prepared channels (cavities) in the approximal surface of the abutment teeth.
CBW anchors are made of titanium (6A 1-4V ELI Alloy for surgical implant applications) or zirconium (grade TZ-3YS).
CBW anchors compare with retentive and splinting pins, because both devices are placed permanently into teeth, the position has to be determined by checking X-rays and both devices are made of bio-compatible dental materials. The devices differ from their purpose. CBW anchors are placed to increase retention of adhesive bridges. Retentive and splinting pins are placed to provide retention and stabilization for restorations in the tooth or for joining two or more teeth together.

Performance testing
CBW anchors can endure three times greater chewing pressures than a person can maximally squeeze (appr. 1350 Newton, Test-Report ,College of Dental Science, University of Nijmegen, the Netherlands, 1999) CBW anchors comply with harmonized standards according to the derective for medical devices 93/42/EEC, EN 46002, EN 1441 standards. CBS International BV , the manufacturer of CBW anchors which are CE marked, nr. CE 0301, is ISO 9002 certified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 9 2000

Ms. Patricia E. Jansen
CBS International BV
Grote Market 3-5
1315 Ja Almere
THE NETHERLANDS

Re: K002693
Trade Name: CBW Bridge System (Consisting of CBW Anchors CBW micro-handpiece and burs)
Regulatory Class: I
Product Code: EBL
Dated: August 25, 2000
Received: August 29, 2000

Dear Ms. Jansen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002693

Device Name: CBW anchors

Indications For Use:

The CBW Bridge System is indicated to improve retention of fixed prostheses. The device is intended to place retentive anchors in proximal teeth.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
510(k) Number K002693